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Joan Claybrook, President



August 17, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane — Room 1061
Rockville, MD 20852

**Re: Docket No. 98F-0165** — "Irradiation in the Production, Processing and Handling of Food"

To whom it may concern:

Under the provisions of 21 CFR 12.24, Public Citizen is requesting a formal evidentiary public hearing for the purposes of revoking the Food and Drug Administration's ruling on Docket No. 98F-0165 — "Irradiation in the Production, Processing and Handling of Food" (65 FR 45280-45282).

We have identified and seek to present at a public hearing genuine and substantial issues containing evidence that raise material issues of fact and that question in a material way the underpinnings of this ruling.

(1) At 65 FR 45281, a 1990 study co-authored by Donald Thayer is cited and it is stated: "*S. enteritidis* was found to have similar sensitivities to ionizing radiation as five other strains of *Salmonella*." In truth, Thayer et al stated: "*S. enteritidis* was significantly more resistant to ionizing radiation than the other five strains of *Salmonella* tested."[1]

By misstating the findings of Thayer et al, the FDA gives the false impression that the same level of radiation can be used to eliminate *S. enteritidis* as other strains of *Salmonella*. This is a significant point, as *S. enteritidis* is a particularly harmful strain of the bacteria. Left unaddressed is whether the approved dose of radiation would be sufficient to adequately eliminate *S. enteritidis*.

(2) At 65 FR 45281, it is stated that, in one study, "shell eggs irradiated at 1.0 kGy and stored for 24 days contained approximately 72 RE's" of vitamin A, compared to 95 RE's contained in fresh unirradiated eggs — a retention rate of 76 percent.

This statement is misrepresentative.

98F-0165

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The original petition had been amended from requesting the approval of a maximum dose of 1.7 kGy to a maximum dose of 3 kGy. According to an internal FDA memorandum cited in the Federal Register, with such a dosage increase "there will be an increase in the degradation of the food components, i.e. protein and vitamins.[2] The memorandum states that, according to one study, the vitamin A retained by egg yolk irradiated at 3.1 kGy and stored for 2, 15 and 33 days was 41.8 percent, 35.5 percent and 20.1 percent, respectively.

The petition was amended on December 22, 1999. By this time, however, the two lengthiest and most in-depth analyses of the petition had already been submitted — based on the lower maximum dosage level of 1.7 kGy.[3,4] After the petition was amended, three brief analyses were submitted, two of which stated that egg yolk irradiated at 3.1 kGy and stored for 33 days retained only 20.1 percent of vitamin A.[5,6] The Federal Register filing makes no mention of this substantial vitamin loss.

(3) The FDA's analysis of the effects of irradiation on egg yolk carotenoids is based on doses of 0.5 kGy and 1.0 kGy.[7] This is far below the maximum level of 3.0 kGy approved in the ruling. Accordingly, this analysis flawed.

(4) The two analyses written before the petition was amended base their conclusions that irradiated eggs are safe for human consumption on a maximum dose of 1.7 kGy. The three analyses written after the petition was amended to request a maximum dose of 3.0 kGy only specifically address issues related to vitamin depletion and D-10 values. Numerous issues raised in the two initial analysis were not updated after the petition was amended. These issues should be re-addressed based on the higher maximum dose of 3.0 kGy.

(5) Lastly but not least importantly, the ruling does not follow the all of the recommendations of the Bureau of Foods Irradiated Food Committee (BFIFC). In its final report of 1980, the BFIFC stated: "Foods irradiated at doses above 100 Krad [1kGy] and comprising more than 0.01% of the diet are estimated to contain URPs [Unique Radiolytic Products] in sufficient quantity to warrant toxicological evaluation. ... [T]ests must be performed on extracts in which the concentration of radiolytic products is maximized." (emphasis in original)[8]

There is no indication in the Federal Register filing or its accompanying seven references that such tests were conducted or reviewed by the FDA before the petition was approved. Without such an analysis, there is no indication whether the URPs formed in eggs irradiated at a dose of 3 kGy would be harmful to humans.

Taken together, these flaws in the ruling represent genuine and substantial issues containing evidence that raise material issues of fact and that question in a material way the underpinnings of the ruling. We request the holding of a formal evidentiary public hearing at the earliest possible date.

Respectfully submitted,

Wenonah Hauter
Director, Public Citizen's Critical Mass Energy and Environment Program

**References**

[1] Thayer, D.W., et al. "Radiation resistance of *Salmonella*." *Journal of Industrial Microbiology*, 5:383-390, 1990

[2] Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, April 11, 2000.

[3] Memorandum from I. Chen, FDA, to W. Trotter, FDA, December 11, 1998.

[4] Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, May 14, 1999.

[5] Memorandum from I. Chen, FDA, to W. Trotter, FDA, March 31, 2000.

[6] Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, April 11, 2000.

[7] Memorandum from K. Morehouse, FDA, to W. Trotter, FDA, May 14, 1999.

[8] "Recommendations for Evaluating the Safety of Irradiated Foods: Final Report." Irradiated Foods Committee, prepared for the director, Bureau of Foods, FDA. July 1980.

**REFERENCES CAN BE VIEWED IN THE DOCKETS MANAGEMENT PUBLIC READING ROOM**
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